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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,981	12/18/2001	Hao Yuan	13774-002001	2606

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EXAMINER

OH, SIMON J

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 04/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/018,981

Applicant(s)

YUAN, HAO

Examiner

Simon J. Oh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 January 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 16-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Papers Received***

Receipt is acknowledged of the applicant's petition for extension of time and the applicant's response, received on 13 January 2003.

### ***Claim Rejections - 35 USC § 112***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite, is rendered moot with the cancellation of that claim.

Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The wording of the claim is unclear as to whether the applicant intends to treat the diseases listed therein simultaneously using a single embodiment of the claimed method. In order to advance prosecution on the pending claims, the diseases listed in Claim 16 will be treated as a Markush group.

Claims 17-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 17-21 all depend upon cancelled Claim 1.

***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 3-5, 7, 12, and 13 under 35 U.S.C. 102(b) is rendered moot with the cancellation of those claims.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 1-15 under 35 U.S.C. 103(a) is rendered moot with the cancellation of those claims.

Claims 16 and 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liu *et al.* in view of Yuan.

The Liu *et al.* article discloses the existence of the *Shengmai Chenggu* tablet, which consists of the leaves of *Cajanus cajan* (L.) Millsp; the tablet is disclosed to be effective for treating necrosis of the femoral head. The leaves of *Cajanus cajan* (L.) Millsp are disclosed as

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being effective in treating injury, burn infection, sores, and jaundice; the leaves are also reported to possess anti-septic and anti-inflammation properties (See Page 7). In addition, a process for preparing an extract and a powder from the leaves of *Cajanus cajan* (L.) Millsp is disclosed. The process involves taking a batch of the leaves and cutting into pieces. Water is added in amount that is 10 times that of the leaves. The mixture is heated and boiled 3 times for a duration of 1 hour each time. The filtered solution is concentrated in a vacuum, and the remaining paste is dried and then pulverized into powder (See Page 8, Section 2.1.1). This process is then optimized so that the mixture of leaves and water is boiled 3 times for a duration of 1.5 hours each time (See Page 7, Abstract; and Page 9, Section 4).

The Liu *et al.* article does not disclose a method of treatment comprising the administration of leaves of *Cajanus cajan* (L.) Millsp or an extract thereof for amelioration of hemorheological index, treating angina of coronary heart disease, treating fracture, treating cerebral infarction, or treating osteoporosis.

The Yuan document discloses the use of the leaves of *Cajanus cajan* (L.) Millsp in a medical preparation for curing ischemic necrosis of the femoral head. This medical preparation is reported to prevent microcirculation, promoting blood vessel regeneration, absorbing necrotic bone, and regenerating new bone (See Abstract).

It would be obvious to one of ordinary skill in the art to combine the teachings of Liu *et al.* and Yuan into the objects of the present invention. The Liu *et al.* article teaches the basic method of preparing an extract of the leaves of *Cajanus cajan* (L.) Millsp, as well as the therapeutic properties of such a preparation. The Yuan document also teaches a medical preparation of *Cajanus cajan* (L.) Millsp, as well as disclosing additional therapeutic properties

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of such a composition. One of ordinary skill in the art to combine the references because as stated in *In re Kerkhoven*, 205 USPQ 1069, 1072 (CCPA- 1980), “It is prima facie obvious to combine two compositions, each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose.” As this court explained in *Crockett*, 126 USPQ 186, 188 (CCPA- 1960), the idea of combining them flows logically from their having been individually taught in the prior art. Regarding claim limitations drawn to treatments for specific diseases or conditions, it is the position of the examiner that the general therapeutic properties taught by the prior art obviates these claim limitations. The prior art establishes certain generic features of preparations of *Cajanus cajan* (L.) Millsp, including the absorption of necrotic tissue, promotion of bone health, promotion of blood vessel health, antiseptic properties, wound and sore healing properties, and anti-inflammatory properties. The discovery of treatments for specific conditions laid out by the applicant would be obvious for one of ordinary skill in the art through routine experimentation, in light of the general therapeutic properties of *Cajanus cajan* (L.) Millsp disclosed by the prior art. Thus, the claimed invention as a whole is *prima facie* obvious.

#### ***Allowable Subject Matter***

Claims 17 and 18 could possibly be found allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action, and to include all limitations of Claim 16 which are not directed to the treatment of specific diseases embodied in Claims 19-21, which are rejected under 35 U.S.C. 103(a), set forth above.

***Response to Arguments***

Applicant's arguments, received on 13 January 2003, have been considered but are not found to be entirely persuasive.

The pending claims are directed to methods of treating specific diseases, rather than the prevention of those diseases. That osteoporosis and bone fractures have different causes and pathological mechanisms than ischemic necrosis of the femoral head is irrelevant, and it does not set forth a convincing argument that the treatment of osteoporosis and bone fracture by the administration of *Cajanus cajan* (L.) Millsp is novel over the prior art. A small cut and a minor burn, though having different causes, can both be easily treated with the administration of ointment and an adhesive bandage, for the prevention of infection and improved healing. The disclosure in Yuan gives an attribute to a medical preparation of *Cajanus cajan* (L.) Millsp as being useful for absorbing necrotic bone and, in particular, regenerating new bone. Given this attribute, it is the position of the examiner that one of ordinary skill in the art would find the administration of such a medical preparation as being suitable for the treatment of osteoporosis and fractures, where the growth of new bone is necessary for success of the treatment. Similarly, one of ordinary skill in the art would find the administration of a medical preparation that prevents microcirculation, as disclosed in Yuan, as being suitable in a treatment for the amelioration of the hemorheological index. It is further the position of the examiner that one of ordinary skill in the art, giving the prior art its broadest reasonable interpretation, would find the invention of the Claims 16 and 19-21 obvious in view of the properties disclosed by the prior art. See MPEP § 2111 and 2123.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (703) 305-3265. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.



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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Simon J. Oh  
Examiner  
Art Unit 1615

sj  
March 28, 2003

THURMAN K. PAGE  
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